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10/567,581

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Dan Hashimshony

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11/23/2010

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EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

11/23/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |   |   |  |
|------------------------------|---|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/567,581      | <b>Applicant(s)</b><br>HASHIMSHONY, DAN |  |
|                              | <b>Examiner</b><br>KATHERINE L. FERNANDEZ | <b>Art Unit</b><br>3768                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-60,62-80,82-84 and 86-91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-60,62-80,82-84 and 86-91 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/25/10;7/25/10;8/17/10;8/25/10;9/7/10;9/16/10;9/20/10;9/20/10;9/28/10;10/12/10;10/20/10;11/2/10;11/2/10.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 52, 60, 71 and 78 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims recite that the electromagnetic sensor is a nonirradiative electromagnetic sensor. However, the respective independent claims already claim that the electromagnetic sensor is nonirradiative, and therefore the above claims do not constitute a further limitation.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-4,6-8,10-11,13-18,21-24,30-31,33-34,36-41,69-78,82,86-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Iddan (US Patent No. 6,936,003).

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With regards to claims 1,18,21,69, 41,71 and 82 Iddan discloses an endoscope and a method for tissue characterization using the endoscope, which comprises: an intracorporeal portion, configured for insertion into a body, and including: a nonirradiative electromagnetic sensor for tissue characterization (column 3, lines 28-51; column 3, line 62-column 4, line 25), configured to be placed proximally to an edge of a tissue for characterization, said characterization being without penetration by said non-irradiative electromagnetic sensor of the tissue being characterized (column 5, lines 6-19, lines 36-62; column 3, lines 1-6; column 14, lines 51-55; note that placement of endoscope/sensor in body (i.e. blood vessel) results in sensor being placed proximally to edge of a tissue (i.e. vessel wall) for characterization); a communication line, on which the electromagnetic sensor is mounted (column 4, lines 39-59, see Figure 1A); an extracorporeal portion, configured for manipulating the intracorporeal portion (column 3, lines 18-27; column 5, lines 6-19); and a control station (column 5, lines 21-62). See Figure 1A.

With regards to claims 2 and 22, the communication line is formed as an instrument bundle (column 4, lines 39-59; see Figure 1A).

With regards to claims 3 and 23, the instrument bundle extends beyond a distal-most end of the endoscope, with respect to an operator (column 3, line 18-51; column 3, line 62-column 4, line 25; see Figure 1A) , and a distal-most end of the instrument bundle may be manipulated, extracorporeally, to bring the electromagnetic sensor to contact with tissue, for characterization (column 5, lines 6-19, lines 36-62).

With regards to claim 4, the intracorporeal portion further includes an instrument channel, and the electromagnetic sensor for tissue characterization is inserted into the instrument channel (column 4, lines 39-59; see Figure 1A).

With regards to claims 6, 24, 30 and 86, the endoscope further includes a catheter, wherein the electromagnetic sensor is inserted into the catheter, and the catheter is inserted into the instrument channel (column 3, lines 28-51; column 3, line 62-column 4, line 25; column 4, lines 39-59; see Figure 1A).

With regards to claims 7, 31 and 87, the catheter extends beyond a distal-most end of the endoscope, with respect to an operator, and a distal-most end of the catheter may be manipulated independently of the distal-most end of the endoscope (column 3, lines 28-51; column 3, line 62-column 4, line 25; column 4, lines 39-59; see Figure 1A).

With regards to claim 8, the intracorporeal portion further includes an optical channel for an optical instrument (column 3, lines 28-51; column 3, line 62-column 4, line 25; column 4, lines 39-67; see Figure 1A).

With regards to claims 10-11 and 33-34, the intracorporeal portion further includes a second instrument (i.e. optical sensor, temperature sensor, impedance sensor, etc.) (column 3, line 28-column 4, line 25; see Figure 1A).

With regards to claims 13, 17, 36, 40 the intracorporeal portion is designed for motion in a body lumen (i.e. a gastrointestinal tract, a colon, a vagina, a uterus, a blood vessel, etc.) (column 3, lines 1-6; column 5, lines 6-19, 36-62).

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With regards to claims 14 and 38-39, the intracorporeal portion is designed for reaching the lumen by percutaneous insertion (column 3, lines 1-6).

With regards to claim 15, the endoscope is configured for characterizing a tissue along the lumen wall (column 14, lines 49-55).

With regards to claims 16 and 37, the endoscope is configured for characterizing a tissue outside the lumen, by penetrating the lumen wall (column 3, line 62-column 4, line 25; column 14, lines 38-55; column 3, lines 1-6).

With regards to claim 70, the control station further includes at least one of a control unit, control buttons, a keyboard, a read/write device, a signal analyzer, and a display screen (column 5, lines 21-62).

With regards to claims 72-74, the second instrument is configured for taking a biopsy sample, localized surgery, and dispensing medication (column 3, lines 28-51; column 3, line 62-column 4, line 25).

With regards to claims 75-77, the intracorporeal portion includes a cutting tool (column 3, lines 28-51; column 3, line 62-column 4, line 25).

With regards to claims 88-91, the distal-most end of the catheter is manipulated electronically and manually (column 5, lines 6-62).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 5,25-29,44-60 and 62-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan as applied to claims 4 and 24 above, and further in view of Ouchi (US Patent No. 6,203,533).

As discussed above, the above combined references meet the limitations of claim 4 and most of the limitations of claims 44-45,51-60 and 62. Further, with regards to claims 25-29,44,46-51,53-58 and 63-68, Iddan discloses that their method further includes a second instrument inserted in the endoscope and performing a second procedure with the second instrument, wherein the second procedure includes taking a biopsy sample, a localized surgery, dispensing medication, and characterizing the tissue by an additional sensor (column 3, line 28-column 4, line 25).

However, they do not specifically disclose that the electromagnetic sensor for tissue characterization may be removed from the instrument channel and replaced with the second instrument.

Further, they do not specifically disclose inserting a guide wire to the location of the characterized tissue and inserting the second instrument into the instrument channel along the guidewire.

Ouchi discloses an injector instrument, for insertion into a forceps channel of an endoscope, which is inexpensive, is easily fed around bends in a forceps channel, is sufficiently small to be inserted into even a thin forceps channel and is easily cleansed and disinfected (column 4, lines 26-30, 58-67). The injector instrument is removably inserted through a forceps channel of an endoscope (column 10, lines 11-16; column



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14, lines 1-3). A guide tube can be inserted in the forceps channel of the endoscope and the injector instrument inserted along the guide tube (column 20, lines 21-27).

They further disclose that other treatment accessory devices can be inserted in the forceps channel and by doing so the size of the endoscope is not increased (column 23, lines 23-30; column 24, lines 26-45; column 29, lines 31-39).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Iddan to have the electromagnetic sensor be removed from the instrument channel and replaced with the second instrument and insert the second instrument into the instrument channel along an inserted guide wire, as taught by Ouchi, in order to be able to effectively clean and disinfect the electromagnetic sensor, be able to use a variety of instruments without increasing the size of the endoscope and properly position the second instrument (column 4, lines 26-30, 58-67; column 29, lines 31-39).

6. Claims 9, 12, 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan as applied to claims 9, 10, 21 and 33 above, and further in view of Nevo et al. (US Pub No. 2003/0187347).

As discussed above, the above combined references meet the limitations of claims 9, 10, 21 and 33. Iddan further disclose that their method includes inserting an optical instrument (column 3, lines 28-51).

However, they do not specifically disclose that the second instrument, such as an optical instrument, is configured to sense/visually observe the electromagnetic sensor as it makes contact with a tissue.

Nevo et al. discloses that their invention includes the use of a separate set of tracking coils for tracking purposes (i.e. electromagnetic sensor), and a separate set of imaging coils for imaging purposes (i.e. MR sensor) (pg. 6, paragraph [0076], pg.3, paragraph [0029]). The control system controls the set of tracking coils to sense and indicate the location and orientation of the probe within the body cavity and controls the set of imaging coils to image selective areas within the body cavity (pg. 3, paragraphs [0028]-[0029]).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Iddan to have the second instrument be configured to sense/image the electromagnetic sensor, as taught by Nevo et al., in order to enable the instrument to characterize selected areas within the body cavity (pg.3, paragraph [0028]-[0029]).

7. Claims 19-20, 42-43, 80 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan as applied to claims 1,21, 78 and 82 above, and further in view of Bouton (US Pub No. 2003/0036674).

As discussed above, Iddan meets the limitations of claims 1,21, 78 and 82. However, they do not specifically disclose that the tissue characterization relates to the detection of a malignancy or relates to the detection of a pre-cancerous state.

Further, Iddan does not specifically disclose that the nonirradiative electromagnetic sensor includes: a resonating element, formed as a conductive structure, configured to be placed proximally to an edge of the tissue, without penetrating the tissue, and having a diameter-equivalent  $D$ , which defines a cross-sectional area of the resonating element, on a plane substantially parallel with the edge of the tissue; and at least one conductive lead, for providing communication with an external system, wherein the resonating element is configured to resonate at a free-air wavelength range of between about  $\lambda$  and about  $10\lambda$ , wherein  $\lambda$  is at least about ten times the diameter-equivalent  $D$ , and wherein upon receiving a signal in the range of between about  $\lambda$  and about  $10\lambda$ , the electromagnetic sensor is configured to induce electric and magnetic fields, in a near zone, in the tissue, the near zone being a hemisphere having a diameter of substantially  $D$ , beginning with the edge of the tissue, while causing negligible radiation in a far zone, so that the tissue, in the near zone, effectively functions as part of the resonating element, and wherein different tissue types have different resonating responses to the electromagnetic sensor, so that the tissue, in the near zone, may be categorized, by the resonating response to the nonirradiative electromagnetic sensor.

Bouton discloses a sensor element for receiving electromagnetic waves into body tissue that is an improved sensor for detecting elevated or otherwise abnormal levels of fluids in living tissue and can be used to detect tumors (pg. 2, paragraph [0014]-[0015]). Their sensor includes a resonating element (20, 400,420) configured to be placed proximally to an edge of the tissue, without penetrating the tissue (pgs.5-6,

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paragraph [0070], [0073]; pg. 8, paragraph [0087]). The sensor has a conductive structure (420,440,450) having a diameter-equivalent  $D$  (400w), which defines a cross-sectional area of the resonating element, on a plane substantially parallel with the edge of the tissue (see Figure 7D; pg. 8, paragraph [0090]). The resonating element is configured to resonate at a free-air wavelength range of between about  $\lambda$  and about  $10\lambda$ , wherein  $\lambda$  is at least about ten times the diameter-equivalent  $D$  (pg. 10, paragraph [0109]; pg. 11, paragraph [0121]; pg. 6, paragraphs [0074]-[0078], note that other possible wavelength configurations are possible by adapting the design of the antenna). Upon receiving a signal in the range of between  $\lambda$  and about  $10\lambda$ , the sensor is configured to induce electric and magnetic fields, in a near zone, in the tissue, the near zone being a hemisphere having a diameter of substantially  $D$ , beginning with the edge of the tissue, while causing negligible radiation in a far zone, so that the tissue, in the near zone, effectively functions as part of the resonating element (pg. 2, paragraph [0016]; pg. 6, paragraph [0074]-[0075]; pg. 7, paragraph [0080]; pgs. 10-11, paragraph [0112]; see Figures 13-16, 18 and 21-22), and wherein different tissue types have different resonating responses to the electromagnetic sensor, so that tissue, in the near zone, may be categorized by the resonating response to the nonirradiative electromagnetic sensor (pg. 6, paragraph [0075]-[0076]; pg. 5, paragraph [0068]).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Iddan to have the electromagnetic sensor include the above limitations, as Iddan requires a sensor that characterizes tissue and Bouton

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teaches such a sensor that can be used for detecting the presence of tumors in living tissue (pg. 2, paragraph [0014]).

8. Claims 79 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iddan as applied to claim 78 above, and further in view of Hashimshony (US Pub No. 2003/0187366).

As discussed above, the above combined references meet the limitations of claim 78. However, they do not specifically disclose that the nonirradiative electromagnetic sensor is configured for: applying an electrical pulse to the tissue; generating an electrical fringe field in a near-field zone of the tissue, so as to produce a reflected pulse from the near-field zone of the tissue with negligible radiation penetrating the tissue; and detecting the reflected electrical pulse.

Hashimshony disclose a method and apparatus for examining tissue in order to differentiate the examined tissue from other tissue (i.e. differentiate between cancerous and normal, healthy tissue) according to the dielectric properties of the examined tissue (pg. 1, paragraph [0001]). They disclose that their apparatus comprises of applying an electrical pulse to the tissue to be examined via a probe such that the probe generates an electrical fringe field in the examined tissue and produces a reflected pulse therefrom, with negligible radiation penetrating into other tissues or biological bodies near the examined tissue; detecting the reflected electrical pulse; and comparing electrical characteristics of the reflected electrical pulse with respect to the applied

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electrical pulse to provide an indication of the dielectric properties of the examined tissue (pg. 2, paragraphs [0017]-[0018]; pg. 5, paragraph [0059]; see Figures 4 and 6).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the sensor taught by Hashimshony substitute for the electromagnetic sensor of Iddan, as Iddan require a sensor that can provide information of the surrounding tissue and Hashimshony teaches such a sensor.

### ***Response to Arguments***

9. Applicant's arguments with respect to claims 1-60,62-80,82-84 and 86-91 have been considered but are moot in view of the new ground(s) of rejection.

With regards to the Iddan references, Applicant argues that the "electromagnetic sensors are all irradiative: imagers, optical sensing, collect reflected light, spectrometer". However, Examiner notes that the term "**irradiate**" may be defined as "**to emit like rays of light: radiate**" and "**irradiative**" is the adjective form of irradiate. Therefore, the phrase "a **non-irradiative** electromagnetic sensor" can be interpreted as an electromagnetic sensor that *does not* emit rays of light, or *does not radiate*. The image sensor (116) of Iddan does not emit rays of light or any form of radiation. Instead, the image sensor, which may be viewed as the electromagnetic sensor, is disclosed as configured to collect electromagnetic radiation (column 3, lines 34-39). Further, the other sensors disclosed by Iddan (i.e. optical sensor, sensor for determining electrical impedance, spectrometer, etc.) do not radiate, and therefore can be viewed as "non-irradiative" sensors as well. Thus, as the specification fails to define the term "non-

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irradiative”, the term is given its broadest reasonable meaning as defined above, and therefore Iddan meets the above limitation.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. L. F./  
Examiner, Art Unit 3768

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768